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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/591,366	06/09/00	BAIDYA	N 421452000100

GLADYS H MONROY
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO CA 94304-1018

HM22/0709

EXAMINER

MARSCHEL, A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/591,366

Applicant(s)
Baidya et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-48 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 5
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

It is noted as summarized in the enclosed Examiner Interview Summary of July 6, 2001, that the mailing address of the Written Restriction Requirement, mailed October 17, 2000, was incorrect. Thus, this is the mailing of a new Written Restriction Requirement to the correct address to replace the previously misdirected Written Restriction Requirement Office action. This Requirement also incorporates minor changes and minor corrections over the previous Written Restriction Requirement that are deemed appropriate.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-22, drawn to an array comprising a plurality of polynucleotide probes immobilized on a solid support, classified in Classes 422 and 536, subclasses 68.1 and 23.1, respectively.

II. Claim 23, drawn to a method of preparing an array of polynucleotides, classified in Class 536, subclass 25.3.

III. Claims 24 and 32-37; drawn to a method for simultaneously detecting the expression of gene transcripts and kits therefor, classified in Class 435, subclass 6.

IV. Claims 25-31, 47, and 48; drawn to methods of detecting differential expression of at least two subjects, classified in Class 435, subclass 6.

V. Claims 38-43, drawn to a machine readable storage medium with polynucleotide probe data recorded thereon,

classified in Class 702, subclass 20.

VI. Claims 44-46, drawn to a computer based system for detecting differential expression of a multiplicity of gene transcripts, classified in Class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the arrays of Group I can be made by a materially different process of the chemical linkage and buildup of either nucleotides or oligonucleotides on the various regions of the array in order to make the array versus the single step immobilization of fully complete polynucleotides on each region as required in the practice of Group II. Alternatively, primers may be immobilized on each array region followed by extension with the appropriate template and polymerase to result in the array of Group I. Thus, the distinctness of Groups I and II is supported by numerous alternatives for the making of the arrays of Group I versus the method of Group II. Similarly, Group II is distinct from all of the other Groups in that either the actual making of an array is

not required as for Group V and that methods of use of the synthesized arrays have multiple distinct usages as summarized below.

The array Group I is also distinct from the computer medium Group V in that they are physically different compositions which can be utilized in distinct methods as well as made via distinct methods. The medium of Group V can be utilized in completely computer modeling/calculation database methods for predicting expression models without any array usage for actual measurement. Additionally, the computer medium of Group V can be prepared without any array preparation. This also causes Group V to be distinct from the other invention Groups in that Group V can be made and utilized without any array synthesis as required for the practice of the other method Groups.

The inventions of Group I and Groups III, IV, and VI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the array of Group I can be used in the distinct processes of the inventions of Groups III, IV, and VI. One use is directed to gene transcript expression analysis which is most commonly utilized in drug evaluation for use with one subject

under different drug versus control treatment conditions and the other expression Groups are directed to screening via hybridization reactions between subjects for comparison thereof without the common usage of drug evaluation or the use of database mining as required in Group VI.

As summarized above the Groups III, IV, and VI are directed to distinct inventions. Group III requires simultaneous gene transcript analysis where none of Groups IV or VI require such simultaneous analysis nor only evaluating single subject gene transcript analysis as commonly utilized for drug screening. Groups IV and VI are directed to special differential gene transcript expression analysis with Group IV between subjects without database mining requirements versus Group VI which is also drawn to the analysis of inter-subject differential gene transcript expression but with database mining.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in

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compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

July 6, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER